# Complete Summary

## GUIDELINE TITLE

(1) Prevention and control of meningococcal disease. Recommendations of the Advisory Committee on Immunization Practices (ACIP). (2). Notice to readers: revised recommendations of the Advisory Committee on Immunization Practices to vaccinate all persons aged 11--18 years with meningococcal conjugate vaccine.

## BIBLIOGRAPHIC SOURCE(S)

Bilukha OO, Rosenstein N. Prevention and control of meningococcal disease. Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep 2005 May 27;54(RR-7):1-21. [146 references] PubMed

Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices. Revised recommendations of the Advisory Committee on Immunization Practices to Vaccinate all Persons Aged 11-18 Years with Meningococcal Conjugate Vaccine. MMWR Morb Mortal Wkly Rep 2007 Aug 10;56(31):794-5. [6 references] PubMed

## GUIDELINE STATUS

This is the current release of the guideline.

This addendum updates a previous version: Centers for Disease Control and Prevention. Notice to readers: improved supply of meningococcal conjugate vaccine, recommendation to resume vaccination of children 11--12 years. MMWR Recomm Rep 2006 Nov 3;55(43):1177. [2 references]

## ** REGULATORY ALERT **

## FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- September 11, 2007, Rocephin (ceftriaxone sodium): Roche informed healthcare professionals about revisions made to the prescribing information for Rocephin to clarify the potential risk associated with concomitant use of Rocephin with calcium or calcium-containing solutions or products.
- October 23, 2006 update, Menactra (Meningococcal Conjugate Vaccine): Updated alert to consumers and health care providers regarding reports of Guillain Barre Syndrome (GBS) following administration of Meningococcal Conjugate Vaccine A, C, Y, and W135.

- October 3, 2005, Menactra (Meningococcal Conjugate Vaccine): The U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) notified consumers and health care providers of five reports of Guillain Barre Syndrome following administration of Meningococcal Conjugate Vaccine A, C, Y, and W135 (trade name Menactra).

Note from the National Guideline Clearinghouse and the Centers for Disease Control and Prevention (CDC): On October 6, 2005, CDC reported that, to date, evidence is insufficient to conclude that Menactra® Meningococcal Conjugate Vaccine (MCV4) causes Guillain-Barré Syndrome (GBS). An ongoing known risk for serious meningococcal disease exists. Therefore, CDC is recommending continuation of current vaccination strategies. Whether receipt of MCV4 vaccine might increase the risk for recurrence of GBS is unknown; avoiding vaccinating persons who are not at high risk for meningococcal disease and who are known to have experienced GBS previously is prudent. See the CDC Web site for the complete report.

An October 20, 2006, update of this report summarizing nine additional GBS cases reported to the Vaccine Adverse Event Reporting System (VAERS) during March 2006 to September 2006, is also available from the CDC Web site.

## COMPLETE SUMMARY CONTENT



## SCOPE

### DISEASE/CONDITION(S)

Meningococcal disease

### GUIDELINE CATEGORY

Prevention

### CLINICAL SPECIALTY

Family Practice
Infectious Diseases

Internal Medicine
Pediatrics
Preventive Medicine

## INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Nurses
Physician Assistants
Physicians
Public Health Departments

## GUIDELINE OBJECTIVE(S)

### August 2007 Addendum

To provide updated recommendations to healthcare providers regarding routine vaccination with meningococcal conjugate vaccine

### May 2005 Guidelines

- To update previous reports from the Advisory Committee on Immunization Practices (ACIP) concerning prevention and control of meningococcal disease
- To provide recommendations regarding use of the new meningococcal conjugate vaccine (MCV4) as well as updated recommendations on use of the meningococcal polysaccharide vaccine (MPSV4) and on antimicrobial chemoprophylaxis

## TARGET POPULATION

For vaccination:

- Adolescents and young adults (aged 11-18 years)
- Groups at increased risk:
    - College freshmen living in dormitories
    - Travelers to areas in which meningococcal disease is hyperendemic or epidemic
    - Microbiologists and other laboratory personnel who are routinely exposed to isolates of Neisseria meningitidis
    - Certain populations experiencing outbreaks of meningococcal disease
    - Military recruits
    - Patients with anatomic or functional asplenia
    - Patients with terminal complement deficiency

For postexposure chemoprophylaxis:

- Close contacts of a patient with invasive meningococcal disease, including household members, day care center contacts, and anyone directly exposed to the patient's oral secretions

- Travelers who had direct contact with respiratory secretions from an index-patient or anyone seated directly next to an index-patient on a prolonged flight (i.e., one lasting 8 or more hours)

### INTERVENTIONS AND PRACTICES CONSIDERED

1. Vaccination with meningococcal conjugate vaccine (MCV4) [Menactra™] or meningococcal polysaccharide vaccine (MPSV4)[Menomume®]
2. Antimicrobial chemoprophylaxis

### MAJOR OUTCOMES CONSIDERED

- Number of cases and rates of meningococcal disease
- Rates of disease by age
- Vaccine immunogenicity and efficacy
- Duration of vaccine-induced clinical protection
- Incidence of adverse events associated with vaccine administration
- Cost effectiveness

## METHODOLOGY

### METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

### NUMBER OF SOURCE DOCUMENTS

Not stated

### METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

### METHODS USED TO ANALYZE THE EVIDENCE

Review

### DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

## DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

### August 10, 2007 Addendum

The Advisory Committee on Immunization Practices (ACIP) meningococcal vaccine workgroup reviewed updated data on meningococcal polysaccharide vaccine (MCV4) use and supply projections and data presented previously on the epidemiology of meningococcal disease, safety, and the cost-effectiveness of MCV vaccination strategies. On the basis of these data, expert opinion of the workgroup members, and feedback from partner organizations, the workgroup revised the MCV4 recommendations, which were approved by ACIP at the June 2007 meeting.

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

## COST ANALYSIS

### Cost-Effectiveness Analysis of Meningococcal Polysaccharide Vaccine (MPSV4) Among College Students

From a societal perspective, the economic costs and benefits of vaccinating 1) a cohort of 591,587 freshmen who live in dormitories and 2) all freshmen enrolled in U.S. colleges, regardless of housing status (N = 2.4 million) were evaluated, on the basis of an assumption that the benefits of vaccination would last 4 years. Best- and worst-case scenarios were evaluated by varying the cost of vaccine and administration (range: $54-$88), costs per hospitalization ($10,924-$24,030), the value of premature death on the basis of lifetime productivity ($1.3 million-$4.8 million), the cost per case of vaccine side effects ($7,000-$24,540/1 million doses), and the average long-term cost of treating a case of sequelae of disease ($1,298-$14,600). Vaccination coverage (60% and 100%, respectively) and vaccine efficacy (80% and 90%, respectively) also were varied for evaluation purposes.

Vaccination of freshmen who live in dormitories would result in the administration of approximately 354,950-591,590 doses of vaccine each year, preventing 16-30 cases of meningococcal disease and one to three deaths each year. The cost per case prevented would be an estimated $617,000-$1.85 million, at a cost per death prevented of $6.8-$20.4 million and a cost per life-year saved (LYS)* of $62,042-$489,185. Vaccination of all freshmen would result in the administration of approximately 1,364,400-2,274,000 doses of vaccine each year, preventing 37-69 cases of meningococcal disease and two to five deaths each year. The cost per case prevented would be $1.4-$2.9 million, at a cost per death prevented of $22-$48 million. These data are similar to data derived from previous studies.

## Cost-Effectiveness Analysis of Meningococcal Conjugate Vaccine (MCV4) Among Adolescents Aged 11 Years

From a societal perspective, the economic costs and benefits of vaccinating a cohort of approximately 4,238,670 U.S. adolescents aged 11 years were evaluated, on the basis of an assumption that the benefits of vaccination would last 22 years. A multivariable (Monte Carlo) analysis was performed in which multiple parameters were varied simultaneously over specified probability distributions. These parameters included disease incidence (46-120% of the 10-year average), case fatality ratio (34-131% of the 10-year average), rates of longterm sequelae, acute meningococcal disease costs (i.e., inpatient care, parents' work loss, and public health response), lifetime costs of meningococcal disease sequelae, and cost of vaccine and administration (range: $64-$114). Vaccination coverage (16-95%) and vaccine efficacy (39-99%) also were varied for evaluation purposes.

Median program costs for vaccination of adolescents aged 11 years would be $227 million (5th-95th percentile: $158-$406 million). If a 3% discount rate were used for costs and benefits, during a 22-year period, vaccination among adolescents would prevent 270 cases and 36 deaths (21 cases and three deaths in the first year). The median cost would be $633,000 (5th-95th percentile: $329,000-$1,299,000)/case prevented; $5.0 million (5th-95th percentile: $2.4-$10.9 million)/death prevented; and $121,000 (5th-95th percentile: $69,000-$249,000)/LYS saved.

## Cost-Effectiveness Analysis of a Catch-Up Vaccination Campaign with MCV4

The direct and indirect (herd immunity) benefits of a onetime catch-up vaccination campaign with MCV4 of adolescents aged 11-17 years followed by routine annual vaccination of adolescents aged 11 years were analyzed. For this purpose, a probabilistic model of disease burden and economic impacts was built for a 10-year period with and without an adolescent catch-up program. U.S. age- and serogroup-specific surveillance data on incidence and case fatality rates were used, as were hypothetical age-specific reductions in attack rates among unvaccinated persons obtained on the basis of U.K. data. Medical, work loss, and public response costs were estimated with and without a catch-up campaign, as were lifetime costs of meningococcal disease sequelae. After disease and vaccination program costs were projected, estimated costs per case averted, deaths prevented, LYS, and quality-adjusted life years (QALY)** saved were estimated.

With herd immunity effects equivalent to recent experience in the United Kingdom, catch-up vaccination of adolescents plus an added routine program would prevent 5,263 cases during a 10-year period, a 32% reduction in the number of cases. Excluding program costs, the catch-up program would save $338 million in medical and public response costs and $591 million in time off from work, long-term disability, and premature death. At a hypothetical cost of $83 per vaccinee, a catch-up vaccination program (including 9 years of routine vaccination) would cost society approximately $3.6 billion (45% of this sum in the first year). At a 3% discount rate, the catch-up program would cost society $532,000/case averted, $5.9 million/death prevented, $138,000/LYS, and

$64,000/QALY saved. A 20% reduction in herd immunity effects would increase the cost per LYS by $21,000; a $30 decrease in the cost of vaccination would decrease the cost per LYS by $55,000. On the basis of the assumption that herd immunity can be generated, targeting only those U.S. counties in which the disease is highly endemic would decrease the cost per LYS by two thirds.

Catch-up vaccination of adolescents can have a substantial impact on disease burden and costs. However, these data demonstrate that catch-up and routine vaccination programs with MCV4 among adolescents are more costly per health outcome than existing vaccination strategies for Hib and S. pneumoniae. Compared with routine vaccination of children aged 11 years, catch-up vaccination could cost up to 20% more/LYS.

* The number of life-years saved as a result of a preventive intervention (i.e., the number of potential years of life expected if disease-specific events leading to premature death not occur [healthy life expectancy]). The number of lifeyears saved will be less or at the most equal to the number of potential years lost pre-intervention. Because life expectancy is age-specific, life-years saved is often calculated as the difference between the age-specific healthy life expectancy and the age when a disease-specific event leading to premature mortality could occur without the intervention.

** A measure based on individual preferences for states of health that assigns a value of 1 to a year of perfect health and 0 to death. QALYs measure not only years of life saved but also functioning and health preserved. QALYs are highly relevant when disease-specific outcomes lead to both mortality (i.e., premature death) and substantial morbidity (i.e., temporal or permanent disability). Thus, effectiveness outcomes are expressed as change in health status.

### METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
Peer Review

### DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Recommendations for vaccination from the following groups were discussed: The American Academy of Pediatrics (AAP) and the American Medical Association (AMA).

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

August 10, 2007 Addendum

In January 2005, a quadrivalent meningococcal polysaccharide-protein conjugate vaccine (MCV4) (Menactra™, Sanofi Pasteur, Inc., Swiftwater, Pennsylvania) was licensed for use among persons aged 11-55 years. In May 2005, the Advisory Committee on Immunization Practices (ACIP) recommended routine vaccination with 1 dose of MCV4 for persons aged 11-12 years, persons entering high school

(i.e., at approximately age 15 years) if not previously vaccinated with MCV4, and other persons at increased risk for meningococcal disease, including college freshmen living in dormitories. Background information regarding meningococcal disease and the vaccine, including a discussion of duration of protection and use of the vaccine for outbreak control, has been published previously.

In June 2007, ACIP revised its recommendation to include routine vaccination of all persons aged 11-18 years with 1 dose of MCV4 at the earliest opportunity. Persons aged 11-12 years should be routinely vaccinated at the 11-12 years health-care visit as recommended by ACIP. ACIP continues to recommend routine vaccination for persons aged 19-55 years who are at increased risk for meningococcal disease: college freshmen living in dormitories, microbiologists routinely exposed to isolates of Neisseria meningitidis, military recruits, travelers to or residents of countries in which N. meningitidis meningitis is hyperendemic or epidemic, persons with terminal complement component deficiencies, and persons with anatomic or functional asplenia.

The ACIP goal is routine vaccination of all adolescents with MCV4 beginning at age 11 years. ACIP and partner organizations, including the American Academy of Pediatrics, American Academy of Family Physicians, American Medical Association, and Society for Adolescent Medicine, recommend a health-care visit for children aged 11-12 years to receive recommended vaccinations and indicated preventive services. This visit is the optimal time for adolescents to receive MCV4. In addition, because the incidence of meningococcal disease increases during adolescence, health-care providers should vaccinate previously unvaccinated persons aged 11-18 years with MCV4 at the earliest possible health-care visit. College freshmen living in dormitories are at increased risk for meningococcal disease and should be vaccinated with MCV4 before college entry if they have not been vaccinated previously. Because of difficulties in targeting freshmen in dormitories, colleges may elect to target their vaccination campaigns to all matriculating freshmen.

The ACIP meningococcal vaccine workgroup reviewed updated data on MCV4 use and supply projections and data presented previously on the epidemiology of meningococcal disease, safety, and the cost-effectiveness of MCV vaccination strategies. On the basis of these data, expert opinion of the workgroup members, and feedback from partner organizations, the workgroup revised the MCV4 recommendations, which were approved by ACIP at the June 2007 meeting.

The 2005 ACIP MCV4 recommendation was influenced by concern that implementation of MCV4 recommendations might be hindered by reduced vaccine supply during the first few years of production. In 2005 and 2006, peaks in demand were observed during the months when children were returning to school after summer vacation, leading to limited vaccine availability. However, as of June 2007, ACIP expects supply of MCV4 to be sufficient to meet increased vaccine demand resulting from the revised recommendations. ACIP anticipates that recommending vaccination of all persons aged 11-18 years will improve MCV4 vaccination coverage in this age group and simplify provider decisions to vaccinate.

ACIP encourages health-care providers to vaccinate with MCV4 throughout the year to minimize seasonal increases in demand during July and August when

students prepare to return to school from summer vacation. Vaccine providers should administer MCV4 and Tdap (tetanus toxoid, reduced diphtheria toxoid and acellular pertussis) vaccine to persons aged 11-18 years during the same visit if both vaccines are indicated and available. If simultaneous vaccination is not feasible (e.g., a vaccine is not available), MCV4 and Tdap can be administered using any order of administration. When making decisions about timing of vaccination, providers should consider that eligibility for the Vaccines for Children Program ends at age 19 years.

Guillain-Barré syndrome (GBS) has been associated with receipt of MCV4. Persons with a history of GBS might be at increased risk for postvaccination GBS; therefore, a history of GBS is a relative contraindication to receiving MCV4. Persons recommended to receive meningococcal vaccination who have a history of GBS (or their parents) should discuss the decision to be vaccinated with their health-care provider. Meningococcal polysaccharide vaccine (MPSV4) is an acceptable alternative for short-term protection against meningococcal disease (3-5 years). Providers who have questions about ordering MCV4 or MPSV4 may contact Sanofi Pasteur by telephone at 1-800-VACCINE or online at http://www.vaccineshoppe.com.

## May 2005 Recommendations for Use of Meningococcal Vaccines

### Routine Vaccination of Adolescents

The Advisory Committee on Immunization Practices (ACIP) recommends routine vaccination of young adolescents (defined in this report as persons aged 11-12 years) with meningococcal conjugate vaccine (MCV4) at the preadolescent health-care visit (i.e., a visit to a health-care provider at age 11-12 years, at which time ACIP and other professional organizations [e.g., the American Academy of Pediatrics and the American Medical Association] recommend that persons aged 11-12 years receive appropriate vaccinations and other preventive services). Introducing a recommendation for MCV4 vaccination among persons aged 11-12 years might strengthen the role of the preadolescent health-care visit and have a positive effect on vaccine coverage during adolescence. For those adolescents who have not previously received MCV4, ACIP recommends vaccination before high school entry (at approximately age 15 years) as an effective strategy to reduce meningococcal disease incidence among adolescents and young adults. By 2008, the goal will be routine vaccination with MCV4 of all adolescents beginning at age 11 years. Other adolescents who wish to decrease their risk for meningococcal disease may elect to receive vaccine.

### Other Populations at Increased Risk for Meningococcal Disease

Routine vaccination also is recommended for certain persons who have increased risk for meningococcal disease (see Table below). Use of MCV4 is preferred among persons aged 11-55 years; however, use of the meningococcal polysaccharide vaccine (MPSV4) is recommended among children aged 2-10 years and persons aged >55 years. If MCV4 is unavailable, MPSV4 is an acceptable alternative for persons aged 11-55 years.

The following populations are at increased risk for meningococcal disease:

- College freshmen living in dormitories
- Microbiologists who are routinely exposed to isolates of Neisseria meningitidis
- Military recruits
- Persons who travel to or reside in countries in which N. meningitidis is hyperendemic or epidemic, particularly if contact with the local population will be prolonged
- Persons who have terminal complement component deficiencies
- Persons who have anatomic or functional asplenia

Because of feasibility constraints in targeting freshmen in dormitories, colleges can elect to target their vaccination campaigns to all matriculating freshmen. The risk for meningococcal disease among nonfreshmen college students is similar to that for the general population of similar age (age 18-24 years). However, the vaccines are safe and immunogenic and therefore can be provided to nonfreshmen college students who want to reduce their risk for meningococcal disease.

For travelers, vaccination is especially recommended to those visiting the parts of sub-Saharan Africa known as the "meningitis belt" during the dry season (December-June). Vaccination is required by the government of Saudi Arabia for all travelers to Mecca during the annual Hajj. Advisories for travelers to other countries will be issued when epidemics of meningococcal disease caused by vaccine-preventable serogroups are detected. Travelers' health information is available from the Centers for Disease Control and Prevention (CDC) at 877-FYI-TRIP (toll-free) or at http://www.cdc.gov/travel. Further information concerning geographic areas for which vaccination is recommended can be obtained from international health clinics for travelers and state health departments.

Patients with human immunodeficiency virus (HIV) are likely at increased risk for meningococcal disease, although not to the extent that they are at risk for invasive Streptococcus pneumoniae infection. Although the efficacy of MCV4 among HIV-infected patients is unknown, HIV-infected patients may elect vaccination. For persons aged 11-55 years who have been previously vaccinated with MPSV4, revaccination with MCV4 is not indicated unless vaccination occurred 3-5 years previously and the person still remains at increased risk for meningococcal disease (see Revaccination Section below).

### Adults Aged 20-55 Years

MCV4 is licensed for use among adults aged 20-55 years. It is safe, immunogenic, and likely to provide relatively long-lasting protection against meningococcal disease caused by serogroups A, C, Y, and W-135. The rates of meningococcal disease are low in this age group, and vaccination will decrease but not eliminate risk. Therefore, routine vaccination is not recommended; however, persons who wish to decrease their risk for meningococcal disease may elect to be vaccinated.

### Children <11 Years and Adults Aged >55 Years

MCV4 is not licensed for use among children aged <11 years or adults aged >55 years. Routine vaccination with MPSV4 is not recommended for children aged <2 years because it is relatively ineffective and offers a short duration of protection. Routine vaccination with MPSV4 is not recommended for children aged 2-10 years

and adults aged >55 years who are not identified as being at increased risk for meningococcal disease.

## Outbreaks of Meningococcal Disease

Both MPSV4 and MCV4 are recommended for use in control of meningococcal outbreaks caused by vaccine-preventable serogroups (A, C, W-135, and Y) of N. meningitidis. An outbreak is defined by the occurrence of at least three* confirmed or probable primary** cases of serogroup C meningococcal disease in ≤3 months, with a resulting primary attack rate of ≥10 cases/100,000 population. For calculation of this threshold, population-based rates are used rather than age-specific attack rates. These recommendations are based on experience with serogroup C meningococcal outbreaks, but these principles might be applicable to outbreaks caused by the other vaccine-preventable meningococcal serogroups, including Y, W-135, and A. Both MCV4 and MPSV4 can be used for outbreak control, although use of MCV4 is preferred if the population targeted for vaccination includes age groups for which MCV4 is licensed. Detailed recommendations on evaluation and management of suspected outbreaks of meningococcal disease have been published previously.

*Calculation of attack rates for organization-based outbreaks is most useful for sizable organizations (e.g., certain universities). However, for the majority of organization-based outbreaks with three cases of disease, the rate will be >10 cases/100,000 population. Thus, occurrence of three cases in these settings should prompt consideration of vaccination. In certain situations, public health officials also might consider vaccination after only two primary cases are identified.

**To calculate a primary attack rate, sum all confirmed cases; exclude secondary cases, and count each set of co-primary cases as one case. A primary case is one that occurs in the absence of previous known close contact with another patient. A secondary case is one that occurs among close contacts of a primary patient ≥24 hours after onset of illness in the primary patient. If two or more cases occur among a group of close contacts with onset of illness separated by<24 hours, these cases are considered to be co-primary.

## Administration

For persons aged 11-55 years, MCV4 is administered intramuscularly as a single 0.5-mL dose. MPSV4 is administered subcutaneously as a single 0.5-mL dose to persons aged >2 years. MCV4 and MPSV4 can be administered concomitantly with other vaccines, but at a different anatomic site. Protective levels of antibodies are usually achieved within 7-10 days of vaccination.

## Revaccination

Revaccination might be indicated for persons previously vaccinated with MPSV4 who remain at increased risk for infection (e.g., persons residing in areas in which disease is epidemic), particularly children who were first vaccinated at age <4 years. Such children should be considered for revaccination after 2-3 years if they remain at increased risk. Although the need for revaccination among adults and older children after receiving MPSV4 has not been determined, antibody levels

decline rapidly after 2-3 years, and, if indications still exist for vaccination, revaccination might be considered after 5** years. Repeated vaccination with serogroup A and C polysaccharide vaccine might induce immunologic hyporesponsiveness, although clinical implications of such hyporesponsiveness are not known. Hyporesponsiveness to serogroup C polysaccharide can be overcome by vaccination with serogroup C conjugate vaccine. MCV4 is recommended for revaccination of persons aged 11-55 years; however, use of MSPV4 is acceptable.

ACIP expects that MCV4 will provide longer protection than MPSV4; however, studies are needed to confirm this assumption. More data will likely become available within the next 5 years to guide recommendations on revaccination for persons who were previously vaccinated with MCV4.

**Certain sources recommend revaccination after 3 years.

Precautions and Contraindications

Refer to the "Potential Harms" and "Contraindications" fields in this summary for information.

Table: Recommendations for the Use of Meningococcal Vaccines Among Persons Not Vaccinated Previously

| Population Group | Age Group (yrs) | | | | |
|---|---|---|---|---|---|
| | <2 | 2-10 | 11-19 | 20-55 | >55 |
| General population | Not recommended | Not recommended | A single dose of MCV4 is recommended at age 11-12 years (at preadolescent assessment visit) or at high school entry (at approximately age 15 years) | Not recommended | Not recommended |
| Groups at increased risk:<br>• College freshmen living in dormitories<br>• Certain travelers[2]<br>• Certain | Not usually recommended[1] | A single dose of MPSV4 | A single dose of MCV4 is preferred (MPSV4 is an acceptable alternative) | A single dose of MCV4 is preferred (MPSV4 is an acceptable alternative) | A single dose of MPSV4 |

| Population Group | Age Group (yrs) | | | | |
|---|---|---|---|---|---|
| | <2 | 2-10 | 11-19 | 20-55 | >55 |
| microbiologists[3]<br>• Certain populations experiencing outbreaks of meningococcal disease[4]<br>• Military recruits<br>• Persons with increased susceptibility[5] | | | | | |

[1]MPSV4 (2 doses, 3 months apart) can be considered for children aged 3-18 months to elicit short-term protection against serogroup A disease (a single dose should be considered for children aged 19-23 months).

[2]Persons who travel to or in areas where N. meningitidis is hyperendemic or epidemic are at increased risk of exposure, particularly if contact with the local population will be prolonged. Vaccination is especially recommended to those visiting the "meningitis belt" of sub-Sahara Africa during the dry season (December-June), and vaccination is required by the government of Saudi Arabia for all travelers to Mecca during the annual Hajj. Advisories for travelers are available at http://wwwn.cdc.gov/travel/notices.aspx, http://www.cdc.gov/travel, or by calling CDC's Travelers' Health Hotline at 877-FYI-TRIP (toll-free).

[3]Microbiologists who are routinely exposed to isolates of N. meningitidis should be vaccinated.

[4]The use of vaccination in outbreak settings has been described previously.

[5]Includes persons who have terminal complement component deficiencies and persons with anatomic or functional asplenia.

Antimicrobial Chemoprophylaxis

In the United States, the primary means for prevention of sporadic meningococcal disease is antimicrobial chemoprophylaxis of close contacts of a patient with invasive meningococcal disease (see Table below). Close contacts include 1) household members, 2) child-care center contacts, and 3) anyone directly

exposed to the patient's oral secretions (e.g., through kissing, mouth-to-mouth resuscitation, endotracheal intubation, or endotracheal tube management). For travelers, antimicrobial chemoprophylaxis should be considered for any passenger who had direct contact with respiratory secretions from an index-patient or for anyone seated directly next to an index-patient on a prolonged flight (i.e., one lasting >8 hours). Guidelines for chemoprophylaxis of travelers have been published previously. The attack rate for household contacts exposed to patients who have sporadic meningococcal disease was estimated to be four cases/1,000 persons exposed, which is 500-800 times greater than the rate for the total population. In the United Kingdom, the attack rate among health-care workers exposed to patients with meningococcal disease was determined to be 25 times higher than among the general population.

Because the rate of secondary disease for close contacts is highest immediately after onset of disease in the index patient, antimicrobial chemoprophylaxis should be administered as soon as possible (ideally <24 hours after identification of the index patient). Conversely, chemoprophylaxis administered >14 days after onset of illness in the index patient is probably of limited or no value. Oropharyngeal or nasopharyngeal cultures are not helpful in determining the need for chemoprophylaxis and might unnecessarily delay institution of this preventive measure.

Rifampin, ciprofloxacin, and ceftriaxone are 90-95% effective in reducing nasopharyngeal carriage of N. meningitidis and are all acceptable antimicrobial agents for chemoprophylaxis. Systemic antimicrobial therapy of meningococcal disease with agents other than ceftriaxone or other third-generation cephalosporins might not reliably eradicate nasopharyngeal carriage of N. meningitidis. If other agents have been used for treatment, the index patient should receive chemoprophylactic antibiotics for eradication of nasopharyngeal carriage before being discharged from the hospital.

One recent study has reported that a single 500-mg oral dose of azithromycin was effective in eradicating nasopharyngeal carriage of N. meningitidis. Azithromycin, in addition to being safe and easy to administer, is also available in a suspension form and is approved for use among children. Further evaluation is warranted of both the effectiveness of azithromycin in eradicating carriage of N. meningitidis and potential for development of microbial resistance to this drug if it is widely used for chemoprophylaxis.

Table: Schedule for Administering Chemoprophylaxis Against Meningococcal Disease

| Drug | Age Group | Dosage | Duration and Route of Administration[1] |
|---|---|---|---|
| Rifampin[2] | Children aged <1 mo | 5 mg/kg body weight every 12 hrs | 2 days |
| | Children aged ≥1 mo | 10 mg/kg body weight every 12 hrs | 2 days |
| | Adults | 600 mg every 12 hrs | 2 days |
| Ciprofloxacin[3] | Adults | 500 mg | Single dose |
| Ceftriaxone | Children aged | 125 mg | Single IM[4] dose |

| Drug | Age Group | Dosage | Duration and Route of Administration[1] |
|---|---|---|---|
| | <15 yrs | | |
| Ceftriaxone | Adults | 250 mg | Single IM dose |

[1]Oral administration unless indicated otherwise.

[2]Not recommended for pregnant women because it is teratogenic in laboratory animals. Because the reliability of oral contraceptives might be affected by rifampin therapy, consideration should be given to using alternative contraceptive measures while rifampin is being administered.

[3]Not usually recommended for persons aged <18 years or for pregnant and lactating women because it causes cartilage damage in immature laboratory animals. Can be used for chemoprophylaxis of children when no acceptable alternative therapy is available. Recent literature review identified no reports of irreversible cartilage toxicity or age-associated adverse events among children and adolescents.

[4]Intramuscular.

### CLINICAL ALGORITHM(S)

None provided

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

- Introducing a recommendation for meningococcal conjugate vaccine (MCV4) vaccination among persons aged 11-12 years might strengthen the role of the preadolescent health-care visit and have a positive effect on vaccine coverage during adolescence.
- For adolescents who have not previously received MCV4, vaccination before high school entry (at approximately age 15 years) may be an effective strategy to reduce meningococcal disease incidence among adolescents and young adults.
- Appropriate antimicrobial chemoprophylaxis may prevent sporadic meningococcal disease.

### POTENTIAL HARMS

- Recommended vaccinations can be administered to persons with minor acute illness (e.g., diarrhea or mild upper-respiratory tract infection with or without fever). Vaccination should be deferred for persons with moderate or severe acute illness until the person's condition improves. Any adverse effect suspected to be associated with meningococcal conjugate vaccine (MCV4) or meningococcal polysaccharide vaccine (MPSV4) should be reported to the Vaccine Adverse Event Reporting System (VAERS). More information about VAERS is available at 800-822-7967 (toll-free) or from http://vaers.hhs.gov/.
- Because both MCV4 and MPSV4 are inactivated vaccines, they may be administered to persons who are immunosuppressed as a result of disease or medications; however, response to the vaccine might be less than optimal.
- Studies of vaccination with MPSV4 during pregnancy have not documented adverse effects among either pregnant women or newborns. On the basis of these data, pregnancy should not preclude vaccination with MPSV4, if indicated. MCV4 is safe and immunogenic among nonpregnant persons aged 11-55 years, but no data are available on the safety of MCV4 during pregnancy. Women of childbearing age who become aware that they were pregnant at the time of MCV4 vaccination should contact their health-care provider or the vaccine manufacturer.
- Additional safety information concerning the MCV4 and MPSV4 vaccines, including systemic and local adverse reactions reported in clinical trials, safety of concomitant administration of MCV4 and other vaccines, and serious adverse events reported in all safety studies can be found in the original guideline document. Serious adverse events reported within a 6-month period after vaccination occurred at the same rate (1.3%) in the MCV4 and MPSV4 groups. The events reported were consistent with events expected among healthy adolescent and adult populations.

## CONTRAINDICATIONS

### CONTRAINDICATIONS

- Vaccination with meningococcal conjugate vaccine (MCV4) or meningococcal polysaccharide vaccine (MPSV4) is contraindicated among persons known to have a severe allergic reaction to any component of the vaccine, including diphtheria toxoid (for MCV4), or to dry natural rubber latex.
- Persons with a history of Guillain-Barré syndrome (GBS) might be at increased risk for postvaccination GBS; therefore, a history of GBS is a relative contraindication to receiving MCV4. Persons recommended to receive meningococcal vaccination who have a history of GBS (or their parents) should discuss the decision to be vaccinated with their health-care provider.

## QUALIFYING STATEMENTS

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Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

### IMPLEMENTATION TOOLS

Chart Documentation/Checklists/Forms
Foreign Language Translations
Patient Resources
Quick Reference Guides/Physician Guides
Staff Training/Competency Material

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Staying Healthy

### IOM DOMAIN

Effectiveness
Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

Bilukha OO, Rosenstein N. Prevention and control of meningococcal disease. Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep 2005 May 27;54(RR-7):1-21. [146 references] PubMed

Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices. Revised recommendations of the Advisory Committee on Immunization Practices to Vaccinate all Persons Aged 11-18 Years with Meningococcal Conjugate Vaccine. MMWR Morb Mortal Wkly Rep 2007 Aug 10;56(31):794-5. [6 references] PubMed

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

### DATE RELEASED

2005 May 27 (addendum released 2007 Aug 10)

GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

Advisory Committee on Immunization Practices (ACIP)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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## FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The Centers for Disease Control and Prevention (CDC), their planners, and content experts wish to disclose they have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters. Presentations do not include any discussion of the unlabeled use of a product or a product under investigational use.

## GUIDELINE STATUS

This is the current release of the guideline.

This addendum updates a previous version: Centers for Disease Control and Prevention. Notice to readers: improved supply of meningococcal conjugate

vaccine, recommendation to resume vaccination of children 11--12 years. MMWR Recomm Rep 2006 Nov 3;55(43):1177. [2 references]

## GUIDELINE AVAILABILITY

### May 2005 Guideline

Available from the Centers for Disease Control and Prevention (CDC) Web site.

### August 2007 Addendum

Available from the Centers for Disease Control and Prevention (CDC) Web site.

Print copies: Available from the Centers for Disease and Control Prevention, MMWR, Atlanta, GA 30333. Additional copies can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325; (202) 783-3238.

## AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Quick reference vaccines chart. Available from the Centers for Disease Control and Prevention (CDC) Web site
- Prevention and control of meningococcal disease. Recommendations of the Advisory Committee on Immunization Practices (ACIP). Continuing education activity. Available from the Centers for Disease Control and Prevention (CDC) Web site

Additional resources and information for healthcare professionals, partners, and media regarding meningococcal disease is available from the CDC's National Immunization Program Web site: http://www.cdc.gov/vaccines/vpd-vac/mening/default.htm. Spanish language materials are also available.

## PATIENT RESOURCES

The following is available:

- Meningococcal disease and meningococcal vaccines fact sheet. 2005 Apr.

Available from the Centers for Disease Control and Prevention (CDC) Web site.

## NGC STATUS

This summary was completed by ECRI on August 28, 2000. The information was verified by the guideline developer as of November 17, 2000. This summary was updated by ECRI on June 8, 2005. This summary was updated by ECRI on October 5, 2005 following the U.S. Food and Drug Administration (FDA) advisory on Menactra (Meningococcal Conjugate Vaccine A, C, Y, and W135). This NGC summary was updated on May 24, 2006. This summary was updated by ECRI on October 25, 2006 following the U.S. Food and Drug Administration (FDA) advisory on Menactra (Meningococcal Conjugate Vaccine). This NGC summary was updated by ECRI on December 5, 2006. This summary was updated by ECRI Institute on August 21, 2007. This summary was updated by ECRI Institute on October 3, 2007 following the U.S. Food and Drug Administration (FDA) advisory on Rocephin (ceftriaxone sodium).

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